November 15, 2005

The Honorable Tom Davis
Chairman
Committee on Government Reform
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

In February, I requested that the Committee investigate the growing problem of the manipulation of science by Administration officials for political purposes.[1] I am writing today to renew this request and to urge the Committee to examine one particularly egregious example of the politicization of science: the decision by the Food and Drug Administration to block over-the-counter sales of Plan B, the emergency contraceptive.

Yesterday the Government Accountability Office released a report on the Plan B decision. GAO found that the views of federal scientists were disregarded, their analyses dismissed, and their recommendations ultimately overruled as the agency made what appears to be a preordained decision to reject Plan B. GAO documented multiple ways in which what was supposed to have been an evidence-based decision diverged from standard procedure. According to the GAO report:

- The FDA officials in charge of scientific review for over-the-counter drugs and reproductive drugs disagreed with the decision and did not sign the not-approvable letter as they typically would;

- Scientific review staff were told early in the process that the decision would be made by higher-level management;

- Evidence indicates that the decision not to approve the switch was made before scientific review was completed; and

[1] Letter from Henry A. Waxman to Chairman Tom Davis (Feb. 8, 2005) (online http://www.democrats.reform.house.gov/story.asp?ID=787).

- The rationale for the decision deviated from typical FDA methodology by raising speculative concerns regarding behavioral implications and refusing to extrapolate safety data to younger adolescents.[2]

GAO's thorough investigation raises serious issues that the Government Reform Committee, the principal oversight committee in the House, should pursue. The failure of former FDA Commissioner Mark McClellan to cooperate with GAO investigators and the apparently illegal policy of destroying his emails and memoranda means that Congress does not know the full extent of the involvement of the FDA Commissioner in the decision. In addition, GAO did not examine whether officials at the Department of Health and Human Services or the White House played any role in this apparent subversion of science.

Moreover, GAO's investigation was limited to FDA's May 2004 decision to reject Plan B. After the manufacturer submitted additional information, FDA again failed to approve the application in August 2005. There have been allegations by former FDA officials, such as Dr. Susan Wood, formerly head of the Office of Women's Health, that this second decision was also motivated by politics, not science. These allegations have not been examined by GAO or any congressional committee.

The decisions made at FDA are crucial to the health and safety of our nation. Federal law requires — and the public expects — that these decisions will be based on the best available science, not politics or ideology. For these reasons, I am respectfully requesting that the Committee hold a hearing on FDA's Plan B decisions and the influence of political and ideological considerations on the FDA actions.

In addition to requesting a Committee hearing, I also ask that you join me in requesting documents from FDA, HHS, and the White House relating to the Plan B decisions. Specifically, we should request:

- All communications, written or electronic, and records of phone conversations and meetings, between FDA and other HHS officials, including the Office of the Secretary, regarding Plan B;

- All communications, written or electronic, and records of phone conversations and meetings, between FDA and the White House regarding Plan B;

- All communications, written or electronic, and records of phone conversations and meetings, between HHS and the White House regarding Plan B.

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[2] Government Accountability Office, *Food and Drug Administration: Decision Process to Deny Initial Application for Over-the-Counter Marketing of the Emergency Contraceptive Drug Plan B Was Unusual* (GAO-06-109) (Nov. 14, 2005).

I look forward to working with you in conducting thorough oversight of the Plan B decisions and ensuring the integrity of the scientific process at the Food and Drug Administration and other science-based agencies.

Sincerely,

Henry A. Waxman
Ranking Minority Member